

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wai-Chiu So, et al.

Examiner: WELTER, Rachael

Serial No.: 09/673,872

Art Unit: 1616

Filed: December 4, 2000

Conf. No.: 5826

For: **PHARMACEUTICAL COMPOSITION**

DECLARATION UNDER 37 CFR §1.132

Mail Stop Amendment
P.O. Box 1450
Commissioner for Patents
Alexandria, VA 22313-1450

Dear Commissioner:

I, John Richard Buchta, a citizen of Australia, hereby declare:

1. that I am the Director of Stiefel Research Australia Pty Ltd which is the assignee of U.S. Patent Application No. 09/673,872 ("the '872 Application"), which was filed in the United States on December 4, 2000.
2. The exhibits include Appendix A which is a copy of packaging literature obtained from a package of Men's Rogaine® foam (5% Minoxidil topical aerosol) sold in the United States, showing the ingredients of the product. Rogaine foam is a commercial embodiment of the subject matter recited in amended independent claims 1 and 21 of the '872 Application.
3. The exhibits include Appendix B which is a Table showing the Market Share of Rogaine foam sold in the United States. This data was obtained from a search of publicly available records by The Nielson Company.
4. The exhibits include Appendix C which is a copy of 22 consumer reviews in the United States of Rogaine foam from www.amazon.com.
5. The exhibits include Appendix D which is a copy of Olsen, Elise A., et al. "A multicenter, randomized, placebo-controlled, double-blind clinical trial of a novel formulation of 5% minoxidil topical foam versus placebo in the treatment of androgenetic alopecia in men," J. Am. Acad. Dermatol., Vol. 57, No. 5, pp. 767-774,

Nov. 2007. At page 768, column 1, the article describes a consumer use survey as follows: "Consumer use studies showed that the minoxidil foam vehicle was rated significantly higher on several aesthetic attributes compared with minoxidil solution, including ease of application, lack of dripping, quick absorption and drying, and ability to fit easily into a daily routine."

6. As discussed above, the exhibits include Appendix A which is a copy of packaging literature obtained from a package of Rogaine foam, a commercial embodiment of the subject matter recited in amended independent claims 1 and 21 of the '872 Application.

Amended independent claim 1 recites the following:

A pharmaceutical composition for topical administration, said composition consisting of:

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition, and wherein the minoxidil or salt thereof is not encapsulated;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises propylene glycol, the propylene glycol is present in an amount of less than 10% by weight;

optionally one or more penetration agents selected from the group consisting of dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer a hair generating agent, an antibacterial

agent, a refrigerant, an amino acid, a perfume, an antioxidant, a UV absorber, a dye, a humectants, a thickener, a gelling agent and a color additive,

wherein the apparent pH of the final product is in the range of from approximately 5.0 to 7.0, and wherein the pharmaceutical composition, upon actuation with a propellant, forms a foam or mousse.

Independent claim 21 recites the following:

A method for the treatment of hair loss and related indications in humans, comprising the steps of:

providing a pharmaceutical composition, consisting of

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition, and wherein the minoxidil or salt thereof is not encapsulated;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises propylene glycol, the propylene glycol is present in an amount of less than 10% by weight;

optionally one or more penetration agents selected from the group consisting of dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt,

urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive, and wherein the apparent pH of the final product is in the range of from approximately 5.0 to 7.0,

actuating the pharmaceutical composition with a propellant to form the pharmaceutical composition as a foam or mousse; and

applying topically to the human scalp a therapeutically effective amount of the pharmaceutical composition.

7. Rogaine foam was first approved for sale in the United States in January 2006, and since then has been sold in the United States in marketplaces where the consumer is free to choose from among a variety of products for treating thinning or weak hair/baldness/hair loss.
8. The relevant market is topical treatments for consumers suffering from thinning or weak hair/baldness/hair loss in the United States.
9. As shown in the Table of Appendix B, in 2006 Rogaine foam had a 5% market share based on dollar volume and a 3% market share based on unit volume in the United States. In 2007, Rogaine foam had a 23% market share based on dollar volume and a 14% market share based on unit volume in the United States. In 2008, Rogaine foam had a 27% market share based on dollar volume and a 17% market share based on unit volume in the United States. For January through the end of March of 2010, Rogaine foam had a 28% market share based on dollar volume and a 17% market share based on unit volume in the United States. Since its launch in 2006, Rogaine foam's market share in the United States has increased nearly six times (from 5%/3% in 2006 to 28%/17% in 2010) in less than four years. This increase in market share is a clear indicator of the commercial success of Rogaine foam, resulting from the claimed features discussed above. In addition, for each year, the fact that the market share based on dollar volume data is significantly greater than market share based on unit volume data establishes that Rogaine foam is being sold at a price premium. I believe that this price premium reflects the desirable features of the technology claimed in the '872 Application and embodied in Rogaine foam, namely ease of use and cosmetic elegance.

10. A sampling of positive consumer responses shown in Exhibits C and D evidences the nexus between the commercial success and the subject matter claimed in amended independent claims 1 and 21. More specifically, the positive consumer responses shown in Exhibits C and D establish that the sales of Rogaine foam were a direct result of the unique characteristics of the invention, as claimed in amended independent claims 1 and 21, and not due to other factors.
11. All statements made herein of my own knowledge are true, and are based upon information are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both under the provisions of 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon.

J.R. Buchta

John Richard Buchta
Director, Stiefel Research Australia Pty Ltd

8 July 2010

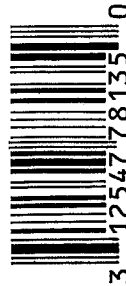
Date

APPENDIX A

To open: Tear at tab and remove top closure.

Drug Facts	Purpose
Active ingredient Minoxidil 5% w/w (without propellant)..... Hair regrowth treatment for men	
Use To regrow hair on the top of the scalp (vertex only, see pictures inside label)	
Warnings For external use only. For use by men only. Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.	
Do not use if <ul style="list-style-type: none">■ you are a woman■ your amount of hair loss is different than that shown on the inside of this label or your hair loss is on the front of the scalp. 5% minoxidil topical foam is not intended for frontal baldness or receding hairline.■ you have no family history of hair loss■ your hair loss is sudden and/or patchy■ you do not know the reason for your hair loss■ you are under 18 years of age. Do not use on babies and children.■ your scalp is red, inflamed, itched, irritated, or painful■ you use other medicines on the scalp	
Ask a doctor before use if you have heart disease	
When using this product <ul style="list-style-type: none">■ do not apply on other parts of the body■ avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.■ some people have experienced changes in hair color and/or texture■ it takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.■ the amount of hair regrowth is different for each person. This product will not work for all men.	
Stop use and ask a doctor if <ul style="list-style-type: none">■ chest pain, rapid heartbeat, faintness, or dizziness occurs■ sudden, unexplained weight gain occurs■ your hands or feet swell■ scalp irritation or redness occurs■ unwanted facial hair growth occurs■ you do not see hair regrowth in 4 months	
May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none">■ apply half a capful 2 times a day to the scalp in the hair loss area■ massage into scalp with fingers, then wash hands well■ see enclosed booklet for complete directions on how to use■ using more or more often will not improve results■ continued use is necessary to increase and keep your hair regrowth or hair loss will begin again	

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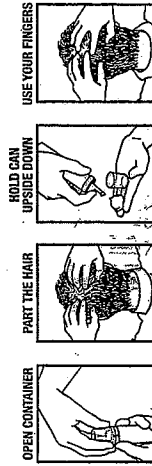
Drug Facts (continued)
Other Information <ul style="list-style-type: none">■ hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months■ see hair loss pictures on right■ before use, read all information on package and enclosed booklet■ keep the package. It contains important information.■ store at controlled room temperature 20° to 25°C (68° to 77°F)■ contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).
Inactive ingredients butane, butylated hydroxytoluene, cetyl alcohol, citric acid, fragrance, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol
Questions? <ul style="list-style-type: none">■ call us at 1-800-ROGAINE (1-800-764-2463)■ visit www.rogaïne.com

THIS PACKAGE CONTAINS:

- Three 60 g (2.11 oz.) Cans of Men's ROGAINE® Foam (three month supply)
- Information booklet with complete directions on how to use and obtain best results

Using the Product:

- To open container: Match arrow on can ring with arrow on cap. Pull off cap.
- Within the hair thinning area, part the hair into one or more rows to maximize scalp exposure.
- The foam may begin to melt right away on contact with your warm skin. If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling the foam.)
- Hold the can upside down and press nozzle to dispense the topical foam product onto your fingers. The total amount of foam applied should not exceed half a capful.
- Using your fingers, spread the foam over the hair loss area and gently massage into scalp and then wash your hands well.
- After each use, close the container to make child resistant by snapping the cap back on to the can.



APPENDIX B

RG RT M 5%MTA FM CAN	2.11OZ	ROGAINE
RG RT M 5%MTA FM CAN 3P	2.11OZ	ROGAINE
RG RT M 5%MTA FM CAN 3P	2.11OZ	ROGAINE
RG RT M 5%MTA FM CAN 3P	2.11OZ	ROGAINE
RG RT M 5%MTA FM CAN 3P	2.11OZ	ROGAINE
RG RT M 5%MTA FM CB	2.11OZ	ROGAINE
RG RT M 5%MTA FM CB	2.11OZ	ROGAINE
RG RT M 5%MTA FM CB	2.11OZ	ROGAINE

RG RT M 5%MTA FM TOTAL

RG RT M 5%MTA FM % OF ALL BRANDS TOTAL

ROGAINE/HAIR GROWTH	ROGAINE
BARRE/HAIR GROWTH	BARRE
CTL BR/HAIR GROWTH	CTL BR
GOOD SENSE/HAIR GROWTH	GOOD SENSE
PREVENT/HAIR GROWTH	PREVENT
ROYAL CROWN/HAIR GROWTH	ROYAL CROWN
AFRICA'S BEST/HAIR GROWTH	AFRICA'S BEST
ALPHARMA/HAIR GROWTH	ALPHARMA
PARNEVU T-TREE/HAIR GROWTH	PARNEVU T-TREE
SUNMARK/HAIR GROWTH	SUNMARK
POSNER/HAIR GROWTH	POSNER
ETHNIC SHEEN MAGIC GRO/HAIR GROWTH	ETHNIC SHEEN MAGIC GRO
DR. MIRACLE'S GRO BALM/HAIR GROWTH	DR. MIRACLE'S GRO BALM
ORGANICS BY AFRICA'S BEST/HAIR GROWTH	ORGANICS BY AFRICA'S BEST
DOCTOR WONDER TEMPLE HEAVEN/HAIR GROWTH	DOCTOR WONDER TEMPLE HEAVEN
DOCTOR WONDER/HAIR GROWTH	DOCTOR WONDER
BB GROWTH OIL/HAIR GROWTH	BB GROWTH OIL
BB GROWTH SERUM/HAIR GROWTH	BB GROWTH SERUM
ORGANIC ROOT STIMULATOR/HAIR GROWTH	ORGANIC ROOT STIMULATOR
STRENGTH OF NATURE PCTV GR RNW/HAIR GROWTH	STRENGTH OF NATURE PCTV GR RNW
SOFTEE/HAIR GROWTH	SOFTEE
DEITY OF HAIR/HAIR GROWTH	DEITY OF HAIR
PREMIER VALUE/HAIR GROWTH	PREMIER VALUE

ALL BRANDS TOTAL

CURRENT 52 WEEKS THRU Mar2010.4		Year 2006		Year 2007		Year 2008	
Dollar Volume	Unit Volume	Dollar Volume	Unit Volume	Dollar Volume	Unit Volume	Dollar Volume	Unit Volume
\$958	32	\$358,455	15,038	\$308,427	12,723	\$33,967	1,263
\$37,156	742	\$81,741	1,737	\$765,493	16,076	\$626,320	12,617
\$20,156,181	424,219	\$1,851,248	38,836	\$10,567,881	218,639	\$15,434,717	323,003
\$0	0	\$109,358	2,401	\$60,815	1,322	\$18,695	406
\$31,250	614	\$35,765	731	\$710,122	14,104	\$761,578	14,788
\$52,865	1,748	\$110,608	4,471	\$714,039	26,264	\$736,951	25,022
\$83,821	2,850	\$237,369	9,598	\$1,417,274	55,477	\$1,355,926	51,652
\$0	0	\$0	0	\$6,475	238	\$0	0
\$20,362,233	430,205	\$2,784,546	72,812	\$14,550,525	344,843	\$18,968,154	428,751
28%	17%	5%	3%	23%	14%	27%	17%

\$46,633,542	1,161,348	\$30,566,202	887,860	\$40,283,214	1,127,113	\$45,585,810	1,175,086
\$74,868	5,612	\$126,538	8,738	\$68,907	5,645	\$55,018	4,196
\$23,139,664	983,272	\$22,007,974	965,346	\$22,580,323	992,478	\$23,002,167	994,641
\$4,147	167	\$2,559	106	\$6,698	250	\$7,228	288
\$11	15	\$0	0	\$0	0	\$0	0
\$0	0	\$0	0	\$0	0	\$0	0
\$645	332	\$260,566	125,802	\$217,529	111,202	\$8,883	4,922
\$52,191	2,197	\$116,293	3,988	\$98,525	3,515	\$64,685	2,555
\$125,187	28,338	\$155,469	36,076	\$154,732	35,587	\$123,165	28,218
\$0	0	\$4,154	212	\$0	0	\$0	0
\$0	0	\$1,639	383	\$258	76	\$0	0
\$0	0	\$1,911	1,910	\$657	642	\$71	71
\$486,000	58,711	\$250,123	32,475	\$538,432	68,341	\$665,677	83,842
\$227,523	46,115	\$138,012	28,008	\$203,065	42,672	\$198,040	40,579
\$11,846	2,370	\$8,387	1,680	\$16,866	3,374	\$16,436	3,287
\$27,813	6,180	\$19,898	4,423	\$30,453	6,768	\$31,563	7,013
\$38,669	6,911	\$11,178	2,067	\$28,515	5,441	\$43,550	8,194
\$61,888	11,182	\$19,865	4,317	\$41,266	8,726	\$53,900	11,122
\$506,149	67,187	\$0	0	\$14,265	1,903	\$345,123	45,486
\$221,637	29,144	\$0	0	\$0	0	\$322,974	40,339
\$61,980	62,266	\$0	0	\$0	0	\$2,254	2,271
\$61,532	5,626	\$0	0	\$1,897	158	\$2,577	215
\$34,993	1,564	\$0	0	\$0	0	\$0	0
\$71,770,287	2,478,537	\$53,690,768	2,103,391	\$64,285,602	2,413,891	\$70,529,119	2,452,325

Year 2009		YTD 2010	
Dollar Volume	Unit Volume	Dollar Volume	Unit Volume
\$958	32	\$0	0
\$48,818	972	\$5,149	111
\$19,577,652	411,379	\$4,989,373	106,916
\$0	0	\$0	0
\$51,426	1,019	\$4,529	88
\$87,241	2,812	\$6,060	232
\$134,704	4,607	\$8,936	290
\$0	0	\$0	0
\$19,900,799	420,821	\$5,014,047	107,637
28%	17%	29%	18%

\$46,152,509	1,155,473	\$11,475,227	291,200
\$68,269	4,903	\$20,169	1,674
\$23,138,625	985,604	\$5,455,778	237,822
\$5,712	225	\$289	14
\$0	0	\$11	15
\$0	0	\$0	0
\$670	518	\$142	71
\$51,365	2,174	\$10,044	463
\$122,528	28,500	\$34,816	8,033
\$0	0	\$0	0
\$0	0	\$0	0
\$0	0	\$0	0
\$537,298	65,239	\$109,462	13,141
\$223,118	45,308	\$56,137	11,226
\$12,515	2,504	\$3,246	649
\$28,791	6,397	\$7,312	1,624
\$42,820	8,301	\$8,188	1,491
\$60,506	11,106	\$16,205	2,880
\$510,389	68,008	\$130,112	17,009
\$250,181	30,616	\$55,092	8,866
\$62,125	63,870	\$14,572	14,627
\$47,840	4,196	\$14,161	1,460
\$0	0	\$34,993	1,564
\$71,315,262	2,482,942	\$17,445,956	613,829

APPENDIX C

ript language="Javascript1.1" type="text/javascript">

Hello, Susanne Hopkins. We have [recommendations](#) for you. (Not Susanne?)

FREE 2-Day Shipping: See details

Susanne's Amazon.com | Today's Deals | Gifts & Wish Lists | Gift Cards

Your Account | Help

Shop All Departments

Search Beauty

14 Cart Wish List

Beauty

Brand Directory

Seller Directory

Bestsellers

Fragrance

Makeup

Skin Care

Hair Care

Bath & Shower

Men's Grooming

Special Offers

Customer Reviews

Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)

22 Reviews

5 star: (14)
 4 star: (6)
 3 star: (1)
 2 star: (1)
 1 star: (0)

Average Customer Review

★★★★★ (22 customer reviews)

Share your thoughts with other customers

[Create your own review](#)

Search Customer Reviews

☒ Only search this product's reviews

The most helpful favorable review

38 of 46 people found the following review helpful:

★★★★★ **First Month Doing Great...**

I've been using this product for about a month now, and while I've never tried any other form of Rogaine or similar product before, it's been a pleasant experience. At first I was unsure about how well I'd remember to apply twice a day. So far I've only missed once. The instructions say to use about half a cap full in your hand (run your fingers under cold water...

[Read the full review >](#)

Published on March 22, 2007 by Doran Luke

> See more [5 star](#), [4 star](#) reviews

The most helpful critical review

2 of 2 people found the following review helpful:

★★★★★ **it helps**

After 8 months of using roaine, my hair is still falling, however, looks fuller, thicker. I was expecting more about this product.

Published 3 months ago by Javier Bedolla

> See more [3 star](#), [2 star](#), [1 star](#) reviews

This product



Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply) by Rogaine
\$89.95 \$58.75

In Stock

[Add to Cart](#)[Add to Wish List](#)

ADVERTISEMENT

[Ad feedback](#)

< Previous | 1 2 3 | Next >

[Most Helpful First](#) | [Newest First](#)★★★★★ **Works on my Frontal Hairline!!**, April 21, 2010By **Elizaul A. Pozo** (new york City) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply) (Health and Beauty)**

I'm 20 years old and since high school I've had a maturing hairline. I started noticing it back when I was 16 in pictures. I always had lighter hair on my temples note I have curly hair (mother African descent). my hairline also looked 3cm higher than when I was younger. 3 months ago my hair line was about 4 fingers above my eyebrows. after 2 bottles I have lots of growth up to my 3rd finger.. and seeing small amounts another 1/2-1cm down.

-the first weeks were only 2 hairs here and 1 hair there type of growth but 2 months in it was very noticeable... I highly recommend. the first 2 weeks u probably wont see any new hairs but then u will i takes some waiting but it'll happen. GOING ON FOR A NEXT ROUND =D

Help other customers find the most helpful reviews

[Report this](#) | [Permalink](#)Was this review helpful to you? [Yes](#) [No](#)[Comment](#)★★★★★ **Wish It Worked Faster**, April 4, 2010By **Del James "Del 7"** (Florida) - [See all my reviews](#)

Amazon Verified Purchase (What's this?)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply) (Health and Beauty)**

I'm 26, started using Rogaine about five months ago. Results didn't show until about four months. My hair loss started becoming noticeable about two years ago when I was 24. Strangely enough I think I've seen more improvement in the front (temples) than in the back. I definitely think the product works but it requires a lot of patience and dedication. Very important note: I've been using Rogaine with a DHT blocker that I take morning and night. From my little research and experience so far, Rogaine re-grows the hair while the DHT stops or slows the hair loss.

Customers who viewed this item also viewed



Rogaine for Men Hair Regrowth Treatment, Easy-to-Use Foam, 2.11-Ounce Cans (Pack of 3) by Rogaine
 ★★★★★ (35)
Buy new: \$50.43 \$42.95

In Stock
 16 used & new from \$37.88



Men's Rogaine Foam-Rogaine Hair Regrowth Treatment by Rogaine
 ★★★★★ (26)
Buy new: \$13.89 - \$59.95



Men's Rogaine 5% Minoxidil Foam 4 month supply (4) 60g (2.11 oz) Cans by Rogaine Men's Foam
 ★★★★★ (2)
Buy new: \$129.99 \$55.60
 In Stock
 11 used & new from \$55.60

Rogaine doesn't seem to do much for the hair loss itself so I think it's necessary to use a DHT blocker to preserve the hair that's already grown.

Here's a not-so-encouraging fact: this product pretty much requires an endless commitment. That means that whatever hair growth is generated by Rogaine is sustainable only through continued use of the product. (Stop using the product and the new hair goes away.) I contemplated doing hair transplant surgery but decided not to because even after surgery it's recommended (if not required) to use a hair re-growth product to maintain the rest of hair around the treated area. Until there's significant breakthrough with stem cell research, Rogaine seems to be the best option.

It would be great if it somehow worked faster. But hair growth just isn't a speedy process.


Help other customers find the most helpful reviews

[Report this](#) | [Permalink](#)

Was this review helpful to you?

1 of 1 people found the following review helpful:

★★★★★ **Foam works better (and is far less messy) than the liquid version - and this price cannot be beat**, March 22, 2010

By **Dieds "Opportunity is limited only by imagina..."**  (Pacifica, Calif.) - [See all my reviews](#)

TOP 1000 REVIEWER VINE VOICE

Amazon Verified Purchase [\(What's this?\)](#)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply) (Health and Beauty)**

I've been using Rogaine for more than a decade and the foam is far (a million times) better than the original liquid. With the foam it is more like hair mousse -- unlike the liquid which is slathered on and leaves your head greasy looking (and feeling).

One thing though is that the foam is far more expensive, mainly because there is no generic version yet available. But for me the price is worth it. However, when I found this option on Amazon I leaped at it -- I'm saving nearly \$30 with every order.

In summary,

- 1) Rogaine works for me -- I've regrown and maintained much of the hair on the top of my head.
- 2) The foam is much better than the liquid -- goes on like hair mousse and isn't messy or greasy
- 3) Ordering from Amazon saves me \$30 when I order 3 month supply.


Help other customers find the most helpful reviews

[Report this](#) | [Permalink](#)

Was this review helpful to you?

2 of 2 people found the following review helpful:

★★★★★ **Minimal results**, March 9, 2010

By **S.K.**  - [See all my reviews](#)

Amazon Verified Purchase [\(What's this?\)](#)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply) (Health and Beauty)**

I used the Rogaine foam faithfully/consistently for 7 months, but I did not see much difference at all. It must be my bad luck to be in the 15% of the population for which this product does not work. That being said, if you're going to try it, here are some things to keep in mind (which other reviewers have noted, as well):

1. You have to apply the stuff twice a day for the rest of your life, or at least as long as you want to try to thicken your hair. Although it's not the worst discipline, I grew weary of having to do it. Too much trouble, I found.
2. It's expensive.
3. As others have said, it works best just to spray it directly on the crown of the head.
4. I don't think the odor is bad. It dissipates after a few minutes, anyway.
5. Definitely use the foam, not the liquid solution. The liquid solution is horribly messy.

Hope you have better luck than I did.

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0 of 1 people found the following review helpful:

☆☆☆☆ **Beware**, February 8, 2010

By **GWBush "TX"** (TX) - [See all my reviews](#)

Amazon Verified Purchase (What's this?)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

There is no such thing as a 4 can -4 month supply. The package only contain 3 cans. Everything else is as advertise.

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2 of 2 people found the following review helpful:

☆☆☆☆ **it helps**, January 30, 2010

By **Javier Bedolla** (northlake, il, US) - [See all my reviews](#)

REAL NAME

Amazon Verified Purchase (What's this?)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

After 8 months of using roaine, my hair is still falling, however, looks fuller, thicker. I was expecting more about this product.

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0 of 4 people found the following review helpful:

☆☆☆☆ **Product came quick but unfortunately for me, it does not work**, August 23, 2009

By **Michael A. Loera "Loera"** (Destin, FL) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

It says on the Rogaine website that the product works in 85% of the people that use it, I guess I am in the 15% that it does not work for. The product is easy to use but if you already have hair on your head than using just the "half capful" it tells you is nearly impossible. A half capful absorbs in my hair before it hits the scalp. Also, the smell is not bad but it can bleach your hair if you put it in and then go out into the sun, like at the beach where I live.

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4 of 6 people found the following review helpful:

☆☆☆☆ **Plain and Simple... It Works!**, July 13, 2009

By **A. Willis "Ol' Night Owl"** (Arizona) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

I have been using Rogaine for about three months now. I started using it on my temples and have had great results. I have recently started using it on the top of my scalp and my receding hairline. Though not clinically tested for either of these areas this is where my hair loss is. What else can I say plain and simple other than... it works.

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2 of 3 people found the following review helpful:

☆☆☆☆ **It works**, April 18, 2009

By **Billie Mack "Diner Guy"** (Boston, MA) - [See all my reviews](#)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

After only one month there is clear evidence that hair is growing. It is light in color and kind of thin, but hair it is. Miracle!

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2 of 4 people found the following review helpful:

★★★★★ **So far so good**, March 10, 2009

By **kalip** - [See all my reviews](#)

Amazon Verified Purchase ([What's this?](#))

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

I have been using Rogaine foam just over eleven months.
I have noticed that the hair at the top and front of my head
has become thicker and the area at the crown of my head has
started filling out.

I shall continue using it to see how it works long term

I have read of people compliant about the odour of this product
however I have noticed none.

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Men's Rogaine Hair Foam

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UltraGrowth Hair Regrowth

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Rogaine Volumizing Shampoo, Thin Hair 12 fl OZ...

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Customer Reviews

Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)

22 Reviews

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3 of 7 people found the following review helpful:

★★★★★ **Rogaine Foam Review**, February 12, 2009By **Blackdog** ☒ - [See all my reviews](#)This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

When I was 23 and I noticed that my hair was starting to thin out. Everyone from college professors to my closest friends made jokes about my hair. I am now in my late 30's and I don't have much left on top. In the past, I've tried every pill, potion and lotion to combat hair loss (including propecia), but nothing really worked.

As far as results are concerned, I'm trying not to go on appearances alone. For example, I've noticed that my head feels less cold when I walk outside in the 30 degree weather now and that there is more resistance when I take my baseball hat off. I can also now run a brush over the top of my head without scraping my scalp and I actually felt the hair move on the top of my head when the wind blew (and this was two week of not using Rogaine Foam).

As of this writing, I would certainly advise the use of Rogaine Foam to those who are losing their hair, whether you are in your early 20's or if you are closer to my age. Since it is similar to mousse in consistency, it is very easy to use and it has given me very good results thus far. I also found Rogaine Foam to be affordable, since it forty dollars for a 3-month supply. I would definitely recommend this hair loss product.

To read my full review, please visit [hubpages.com](#) and type in Blackdog in the search box

Good luck!

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2 of 4 people found the following review helpful:

★★★★★ **It works**, December 14, 2008By **Mike** ☒ (Canada) - [See all my reviews](#)

Amazon Verified Purchase (What's this?)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

It works! Definitely the results can be seen after 3 months. It gives the best balance between its effect and the price. It is easier and faster to apply that the liquid products.

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1 of 4 people found the following review helpful:

★★★★★ **Rogaine is Great**, November 30, 2008By **Canzida Clark "Canzida Clark"** ☒ (Woodbridge, VA) - [See all my reviews](#)

REAL NAME™

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Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply) by Rogaine
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Men's Rogaine Foam-Rogaine Hair Regrowth Treatment by Rogaine
★★★★★ ☒ (26)

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Men's Rogaine 5% Minoxidil Foam 4 month supply (4) 60g (2.11 oz) Cans by Rogaine Men's Foam
★★★★★ ☒ (2)

Buy new: ~~\$129.99~~ **\$55.60**

In Stock

11 used & new from \$55.60

Amazon Verified Purchase (What's this?)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

I recently switched to the Rogaine foam and it is much more user friendly than the liquid. No more dripping and it stays where I put it. My only problem is opening it. Maybe that could be easier.

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Was this review helpful to you? ☐ Yes ☐ No

1 of 7 people found the following review helpful:

★★★★★ **Rogaine**, November 10, 2008

By **Jacqueline D. Logue** ☒ - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

This is a good way to buy Rogaine. It is cheaper and we always receive it timely.

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Was this review helpful to you? ☐ Yes ☐ No

7 of 8 people found the following review helpful:

★★★★★ **Great product!!!!!!!!!!!!!!**, October 14, 2008

By **Juan J. Melo** ☒ (Dominican Republic) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

I have been suffering frontal hair loss for two years, I bought this foam although its not intended for frontal baldness. However, since I started using it, my hair loss got reduced like 80%, so this foam is helping me to keep my hair where it belongs a bit longer.

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Was this review helpful to you? ☐ Yes ☐ No

4 of 5 people found the following review helpful:

★★★★★ **been using for 2 years, works great, quick delivery**, June 23, 2008

By **D. Bennett "boilerdaveb"** ☒ (Columbus OH) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

Swear by this stuff. Use it once a day to maintain hairline that was once mildly to moderately receded.

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Was this review helpful to you? ☐ Yes ☐ No

2 of 3 people found the following review helpful:

★★★★★ **No issues**, June 13, 2008

By **1972d "cactus 134"** ☒ (US) - [See all my reviews](#)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

There were a lot of comments about the odor of this product. There is no reason to be concerned about it. It does have an odor, it smells like soap. I don't even notice it very long after I put it on. Even if it did linger it is only a shampoo/soap smell. It is the 5% solution, even though the description doesn't say it.

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Was this review helpful to you? ☐ Yes ☐ No

9 of 11 people found the following review helpful:

★★★★★ **Medical student skeptic made a believer**, December 1, 2007

By **A. Larson** ☒ (Milwaukee, WI USA) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

My fiancée who didn't know I was using Rogaine for 3 months noticed that I started to regrow hair before I did. You have to be diligent about this stuff and not freak out if you notice you're losing hair early on during the rubbing needed for the application process. I'm going on my 5th month now and the results are well worth

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it. I like the foam too because it can also be used to style your hair.

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19 of 22 people found the following review helpful:

***** **Seems to be working at 2 months!!!**, November 20, 2007

By **Howard "The Med Student"** (Philly, PA) - [See all my reviews](#)

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

I am a 25yr old asian male, who has been thinning hair for about 7yrs now. I have used the liquid version before, but I have to say that the foam is much easier to use; once you get the hang of it.

As I've stated before, I've tried Rogaine before but it didn't seem to do the job, so I discontinued use. I decided to give it another try when I heard of the new foam ,but did not get around to it till now. And so far, I have to say it seems to work.

I do not have significant bald spot at the apex, but rather a frontal thinning (area that isn't indicated by Rogaine). But I figured I had nothing to lose. Initially, I lost more hair but that is what is supposed to happen. 1 1/2 months later, I started to see so-called peach fuzz in the frontal area. And now, after two bottles (2 month), I see that the regrown hair is starting to darken. Not incredibly thick, but darker newly grown hair none the less.

If you expect time machine like effects, this product probably won't do the job. But if you have reasonable goal, this product may definitely help. I mean if I grow enough hair so that I can cover it without noticeability, that is good for me.

It does take sometime to apply it correctly: TO GET IT ON THE SCALP NOT THE HAIR. But it is do-able. One last thing, as others have mentioned, I found it easier to apply directly to scalp rather than using the hand.

I should also note that I did take natural DHT blockers along with the Rogaine. AND don't forget Nizoral or other anti-inflammatory shampoos!!! IMPORTANT!!!

Good Luck to you all

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19 of 22 people found the following review helpful:

***** **Easy to use**, May 23, 2007

By **Matthew J. Braverman** - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

This is much easier to use than the liquid version, though I would suggest applying it directly to the scalp and forget about putting it on your finger than on your scalp. The one drawback is that your hair seems to consume a lot of it and I wonder how much actually makes it to the scalp itself.

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Customer Reviews

Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)

22 Reviews

5 star: (14)
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Average Customer Review

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13 of 17 people found the following review helpful:

★★★★★ **Excellent Product**, March 25, 2007By [Jean Casanova "JeanC"](#) (Venezuela) - [See all my reviews](#)

REAL NAME

This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

The results are not immediately so you have to be patient. But after some weeks you start to see the difference. soon, you will be able to do apply it in seconds and it doesnt interfere with your hairlook. I recommend it 100%

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38 of 46 people found the following review helpful:

★★★★★ **First Month Doing Great...**, March 22, 2007By [Doran Luke](#) (College Park, MD USA) - [See all my reviews](#)This review is from: **Men's Rogaine Foam-Rogaine Hair Regrowth Treatment, 4/2.11 oz. cans (4 Month Supply)** (Health and Beauty)

I've been using this product for about a month now, and while I've never tried any other form of Rogaine or similar product before, it's been a pleasant experience. At first I was unsure about how well I'd remember to apply twice a day. So far I've only missed once. The instructions say to use about half a cap full in your hand (run your fingers under cold water nonetheless), but I found it was much easier to just dispense the foam directly onto my scalp, without worrying about it literally melting in my hand. This way I could easily target the areas I needed most all at once. Sometimes I accidentally do a little too much, and sometimes too little. But the little foam bottle actually does have more in it than I expected. Then I gently rub it in all over my scalp and believe me, the stuff dissolves almost instantly into liquid so you gotta keep rubbing it in until it completely feels dry. Thats when you notice your hair all matte textured like you just used some weird thickening mousse. It's not bad at all. If you already have thin hair like me then it actually kinda helps the styling process to give your hair some body and lift. The smell isn't so bad either. I've heard of other products having weird smells but Rogaine Foam smells decent. It's a little strong at first but goes away soon enough. I should point out that I've been using this product where it hasn't been clinically confirmed to work - in the frontal areas of my scalp and along my receding hairline. I've read and heard about people having success using the product there, so I figured why not. As of now it's hard to say if any new hair is growing, but one thing's for sure - my hair hasn't looked any worse. About 5 years ago I noticed my hair taking the same route as my brother and male cousins - the dave letterman style receding island. It's been slowly getting worse this past year but with the Rogaine Foam I somehow already feel confident the product is working. It's funny how I've heard about other people dismissing Rogaine simply because it's a well known doctor advised solution. And I've personally seen what happens when they decide to go the herbal or "all natural" route, such as all the nonsense you'll find online with all the glorious fake reviews to back it. Sorry, but those products just don't work for people - I've seen it first-hand with my brother and others over the last 5 years. They're now bald. I'm really glad I went with Rogaine - definitely satisfied so far, good luck to everyone! I'll update here if I can. :)

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This product



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Men's Rogaine 5% Minoxidil Foam 4 month supply (4) 60g (2.11 oz) Cans by Rogaine Men's Foam
 ★★★★★ ☒ (2)
 Buy new: ~~\$129.99~~ **\$55.60**
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APPENDIX D

A multicenter, randomized, placebo-controlled, double-blind clinical trial of a novel formulation of 5% minoxidil topical foam versus placebo in the treatment of androgenetic alopecia in men

Elise A. Olsen, MD,^a David Whiting, MD,^b Wilma Bergfeld, MD,^c Jeffrey Miller, MD,^d Maria Hordinsky, MD,^e Rita Wanser, BS,^f Paul Zhang, PhD,^f and Bruce Kohut, DMD^f
Durham, North Carolina; Dallas, Texas; Cleveland, Ohio; Hershey, Pennsylvania; Minneapolis, Minnesota; and Morris Plains, New Jersey

Background: An alternative to currently marketed topical minoxidil solutions is desirable.

Objective: To assess the efficacy and safety of a new 5% minoxidil topical formulation in a propylene glycol-free foam vehicle in men with androgenetic alopecia (AGA).

Methods: This was a 16-week, double-blind, placebo-controlled trial of 5% minoxidil topical foam (MTF) in 352 men, 18 to 49 years old. At week 16, 143 subjects continued on an open-label phase to collect 52 weeks of safety information on 5% MTF.

Results: At week 16 compared with baseline, there was a statistically significant increase in (1) hair counts in the 5% MTF group versus placebo ($P < .0001$) and (2) subjective assessment of improved hair loss condition ($P < .0001$) in the 5% MTF group versus placebo. The 5% MTF was well tolerated over a 52-week period.

Limitations: There was no collection of efficacy data beyond 16 weeks.

Conclusions: We believe that 5% MTF is a safe and effective treatment for men with AGA. (J Am Acad Dermatol 2007;57:767-74.)

Following the initial reports in the 1980s,^{1,2} minoxidil topical solution (MTS) has been a proven mainstay of treatment for male pattern hair loss (MPHL) or androgenetic alopecia (AGA). Two percent MTS is Food and Drug Administration (FDA) approved for both men and women^{3,4} with AGA, and 5% MTS is FDA approved for men with AGA. The vehicle in MTS consists of water, alcohol,

and propylene glycol, the latter increasing in amount with the higher concentration of minoxidil in order to solubilize the minoxidil.

A foam vehicle for delivery of 5% minoxidil (MTF) was identified as an alternative to 5% minoxidil solution. The 5% MTF formulation is a patented, hydroalcoholic, propylene glycol-free formula that is thermolabile and designed to melt at body

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Abbreviations used:

AEs:	adverse events
AGA:	androgenetic alopecia
FDA:	Food and Drug Administration
GPR:	global photographic review
MPHL:	male pattern hair loss
MTF:	minoxidil topical foam
MTS:	minoxidil topical solution
OTC:	over the counter
PK:	pharmacokinetic
TAHC:	target area hair count

temperature. Two preclinical studies evaluated comparative efficacy of the foam and solution vehicles. In the hamster ear model for assessing follicular targeting, the 5% MTF showed increased uptake of minoxidil over the 5% MTS at both 1 and 2 hours of application.⁵ A direct comparison of the efficacy of 5% MTF and 5% MTS was performed in the stump-tailed macaque,⁶ an animal model for AGA in humans.^{7,8} Six macaques were treated topically with either water, 5% MTS or 5% MTF once daily for sequential 4-month trial periods with 3-month washout periods between treatment groups.⁶ Change in target area hair weight between baseline and month 4 of each treatment period was the primary end point. The macaques had an increase in hair weight of 12.40 mg (8.23-26.00 mg) on 5% MTF compared with an increase in hair weight of 9.27 mg (4.96-17.53 mg) on 5% MTS.

Two human pharmacokinetic (PK) studies were completed.⁹ One study compared 5% MTS to 5% MTF and showed that the systemic absorption of the 5% MTF with twice-daily application of 1 g (one-half capful) in men was about half of that observed with 5% MTS with twice-daily application of 1 cc (both 100 mg daily of minoxidil); this was evidenced by the area under the curve of serum minoxidil concentration and maximum serum minoxidil concentration. The second study was an exaggerated-use PK study in men that demonstrated that application of up to 3 g of the 5% MTF or 300 mg of minoxidil (3 times the recommended dose) twice daily resulted in systemic levels that were well below the 21 $\mu\text{g/mL}$ threshold for cardiac-related events and, thus, within acceptable safety margins. Consumer use studies⁹ showed that the minoxidil foam vehicle was rated significantly higher on several aesthetic attributes compared with minoxidil solution, including ease of application, lack of dripping, quick absorption and drying, and ability to fit easily into a daily routine.

A double-blind, placebo-controlled study with an open-label safety extension phase was conducted to assess the efficacy and safety of 5% minoxidil topical foam (MTF) in men with MPHL. The results of this

study, upon which FDA granted approval for the over-the-counter (OTC) use of 5% MTF in January 2006, are presented herein.

METHODS

Subjects

Men aged 18 to 49 years with Hamilton-Norwood patterns IIIv, IV, or V MPHL who were otherwise in good health were enrolled at one of 14 sites in the United States. Subjects were excluded from study participation if they had known sensitivity to minoxidil. Subjects were also excluded if they had used (1) topical minoxidil or any other OTC or prescription medication for hair growth within the past 6 months; (2) 5 α -reductase inhibitors, isotretinoin, radiation to the scalp, or chemotherapy within the past year; (3) botanicals/neutraceuticals for hair regrowth for the past 3 months; or (4) systemic steroids for more than 14 days within the past 2 months prior to enrollment in the study. Men with uncontrolled hypertension or a history of hypotension, any chronic active scalp condition other than AGA, any untreated cancer excluding basal cell carcinoma and squamous cell carcinoma of the nonscalp areas, a history of hair transplants, scalp reduction, or use of hair weaves also were excluded.

Subjects must have agreed to use the same shampoo and to maintain the same hair style, hair length, and hair color during the entire study and to refrain from cutting the scalp hair shorter than 1 inch in length.

Study design

This study was conducted in two phases—a 16-week, double-blind, placebo-controlled phase to evaluate the efficacy and safety of the 5% MTF and a subsequent open-label extension phase to collect 52 weeks of safety data with 5% MTF.

All subjects signed an institutional review board (IRB)-approved informed consent form before participation in the study. Eligible subjects were randomized in a ratio of 1:1 to receive either 5% MTF or placebo twice a day. A 60-g can of study drug was dispensed at baseline and monthly thereafter. Subjects were instructed to dispense one half capful (1 g) of the study drug onto their fingertips and then to apply this directly to the affected vertex balding scalp twice a day. This was to be done after any shampooing or use of a hair dryer, and the study drug was to be allowed to dry naturally. Styling aids were to be applied only after the study drug had dried.

Subjects returned to the study center for compliance and safety evaluations at weeks 1 and 4 and, subsequently, for safety and efficacy evaluations at weeks 8, 12, and 16. At the completion of the

16-week, double-blind phase of the study, subjects were asked to continue on the study using active drug in order to gather a total of 12 months of safety information on 5% MTF. Subjects remained blinded to the treatment (active or placebo) that they had received while on the double-blind portion of the study until month 8 of the extension phase. At that time, if subjects had been on 5% MTF during the initial 16 weeks, the study was discontinued; if they had been receiving placebo during the initial 16 weeks, they continued on the study for an additional 4 months. Those subjects who had been taking active drug for the first 16 study weeks returned to the study center at weeks 24, 32, 40, 48, and 52. Those subjects who had been receiving placebo for the first 16 study weeks returned to the study center at weeks 24, 32, 40, 48, 56, 64, and 68.

Efficacy evaluation

Target area hair counts. Target area hair counts (TAHC) were performed at baseline and weeks 8, 12, and 16. For the double-blind phase of the study, one of the two coprimary efficacy end points was the change in TAHC between baseline and week 16. The percentage change in TAHC between baseline and week 16, while not a primary endpoint, was also evaluated.

At baseline, a circular area on the anterior leading edge of the vertex balding scalp was chosen as the target area for hair counts. A permanent ink dot tattoo was placed for precise localization of the target area on subsequent evaluations. The hairs in an area slightly larger than the 1 cm² target area were clipped to 1 mm. A 35-mm Nikon camera equipped with a device that allowed it to rest on the scalp and fix the distance and lighting of the attached camera (Canfield Scientific, Inc, Fairfield, NJ) was used to take the macrophotographs of the target area. These macrophotographs were sent to Canfield Scientific for processing. The macrophotographs were enlarged to an 8 × 10 size (5.7× magnification), a clear acetate overlay was attached, and all visible (nonvellus) hairs were dot-mapped by a technician trained in the procedure and blinded as to subject, treatment, and time. Dot maps were then translated to hairs by image analysis and a nonvellus TAHC was produced (nonvellus hairs/cm²).¹⁰

Subject assessment. The other coprimary end point was subject assessment of improvement. Subjects were asked to fill out a questionnaire at week 16 that rated their overall hair loss condition in the vertex region compared to baseline. They rated their perception of their hair loss condition compared to baseline using a 7-point scale where -3 = significantly worse, -2 = moderately worse,

-1 = minimally worse, 0 = no change, +1 = minimally improved, +2 = moderately improved, and +3 = significantly improved. To facilitate answering the questionnaire, subjects were provided with standardized Polaroid photographs of the vertex scalp taken at baseline and week 16. For each Polaroid photograph, the subject sat on a stool with the height fixed and placed his head in the stereotactic photographic device to ensure standardization of camera angle, head position, and lighting. Before taking the photographs, the hair in the vertex region was combed radially away from the center to maximize exposure of the hair loss. An attempt was made at the week 16 visit to duplicate the hair combing at baseline in order to facilitate direct comparison between time points.

Global photographic review. Global photographic review (GPR), also called expert panel review or global photographic assessment,¹¹ was a secondary end point. At baseline and weeks 8, 12, and 16, global photographs of the vertex scalp were taken with a 35-mm camera with the same protocol as noted above for Polaroid photographs. The 35-mm slides of baseline and one other study time point were then shown in a side-by-side presentation independently, and in a blinded fashion, to each of 3 experienced global photographic reviewers (Drs Olsen, Whiting, and R. Savin, MD). Room lighting, distance from screen to assessor, and magnification of the projected images were standardized. The global photographic reviewer then assessed the patient's hair loss compared with baseline using the same 7-point scale as subjects. The 3 GPR ratings were then compared. When two ratings were in agreement, the majority score was taken. If all 3 scores were different, the median score was taken.

Safety evaluation

Subjects were assessed at weeks 1, 4, 8, 12, and 16 for any intercurrent events and their potential relatedness to study drug as well as any symptoms of scalp irritation (stinging, burning, itching)—rated by the subjects as none, mild, moderate, or severe. Vital signs and visual assessment of the scalp for any dermatitis (erythema, dryness/scaling, and folliculitis) were rated by the investigator as none, mild, moderate, or severe. The returned container of study drug was weighed at each visit to determine the average dose. A complete blood cell count and serum chemistries and a urinalysis were performed at baseline and at weeks 8 and 16. If there was an event of any cardiac nature at any time point in the study (including a change in blood pressure, pulse, body weight, or hypertrichosis), investigators were instructed to draw blood for a serum minoxidil level.

Table I. Subject demographics by treat group—intent-to-treat population

Demographics	Treatment group	
	Placebo	5% MTF
Age, y		
No.	172	180
Range (min-max)	20.0-49.0	21.0-49.0
Mean (SD)	38.3 (± 7.34)	40.1 (± 6.33)
Race, No. (%)		
White	154 (89.5%)	151 (83.9%)
Black	5 (2.9%)	7 (3.9%)
Hispanic	7 (4.10%)	17 (9.4%)
Asian or Pacific Islander	3 (1.7%)	3 (1.7%)
American Indian or Alaskan	2 (1.2%)	2 (1.1%)
Other	1 (<1%)	—
Duration of hair loss (mo)		
No.	172	180
Mean (SD)	105.9 (67.03)	115.4 (77.03)
Median	96.0	108.0
Range (min-max)	5.0-312.0	12.0-336.0
MPHL No.(%)		
Type IIIv	63 (36.6)	77 (42.8)
Type IV	64 (37.2)	53 (29.4)
Type V	45 (26.2)	50 (27.8)
TAHC		
Mean (SD)	168.9 (48.45)	170.8 (50.4)
Median	167.5	167
Range (min-max)	69.0-324.0	79.0-329.0

MPHL, Male pattern hair loss; MTF, minoxidil topical foam; SD, standard deviation; TAHC, target area hair count.

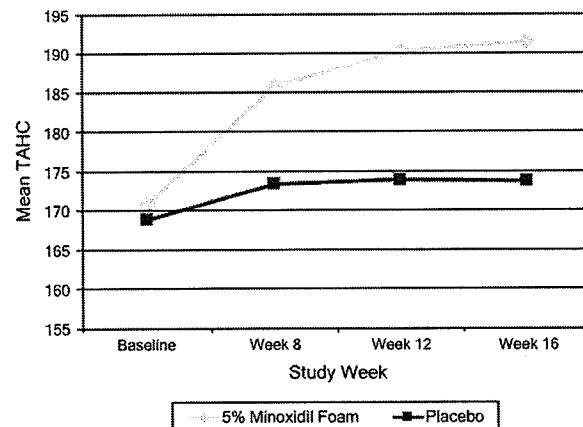
In those subjects participating in the extension study, monitoring for adverse events (AEs) and vital signs was conducted at each visit. Repeat blood tests, urinalysis, and scalp assessments for any irritation (erythema, dryness/scaling, and/or folliculitis) were completed at the final visit of the open-label extension phase.

Statistical analysis

All efficacy and safety analyses were based on the intent-to-treat population. The intent-to-treat population included all randomized subjects.

Change in hair count was analyzed using analysis of covariance at each time point. If a subject's hair count data were not available, the last observation was carried forward. The analysis model included the treatment and center as factors and the subject's age as covariate. The mean difference of change in hair count and the 95% confidence interval of the mean difference were estimated from the model. The normality assumption of the analysis of covariance model was checked using the Shapiro-Wilk test, based on the residuals from the model.

Subject assessment of hair loss condition and the GPR score were analyzed in a way similar to that

**Fig 1.** Mean target area hair counts—intent-to-treat population.

used for change in hair count, except there was no last observation carried forward since these subject assessments were collected only once at week 16.

Descriptive analysis was performed for the safety parameters.

RESULTS

Baseline characteristics

A total of 352 male subjects between the ages of 20 and 49 years with MPHL were enrolled in the study; 172 were assigned to placebo and 180 to 5% MTF (Table I). The mean age of enrolled subjects was 39.2 years old, and the majority of subjects were Caucasian (86.6%). Forty percent of subjects had type IIIv, 33% had type IV, and 27% had type V Hamilton-Norwood hair loss pattern.

Subjects completing study

Three hundred fifteen of the 352 subjects completed 16 study weeks, of which 151 subjects were receiving placebo and 164 subjects were using 5% MTF. The reason for not completing the entire 16 weeks included withdrawn consent (8.1% on placebo, 4.4% on 5% MTF), lost to follow-up (2.3% on placebo, 2.8% on 5% MTF), and a nonserious AE (1.2% on placebo, 1.7% on 5% MTF). Of the 315 subjects completing the 16-week, double-blind phase, 143 entered the extension phase of the study. One hundred fourteen subjects completed 52 weeks on active drug, including 43% of subjects initially randomized to placebo and 57% of subjects initially randomized to 5% MTF. The reason for not completing the entire open-label period included withdrawn consent (11.8% on placebo, 4.0% on 5% MTF), lost to follow-up (8.8% on placebo, 6.7% on 5% MTF), a serious AE (1.5% on placebo, 0% on 5% MTF), and a nonserious AE (2.9% on placebo, 1.3% on 5% MTF).

Table II. Week 16 change from baseline hair count*

	Placebo			5% MTF			Total		
	No.	Mean	SD	No.	Mean	SD	No.	Mean	SD
Overall	156	4.7	19.7	167	20.9	22.5	323	13.1	22.6
Age group (y)									
18-25	11	14.3	17.6	3	22.7	6.7	14	16.1	16.0
26-30	13	7.3	18.3	13	27.1	19.4	26	17.2	21.0
31-35	28	4.9	21.5	19	20.7	17.9	47	11.3	21.4
36-40	33	1.6	21.9	43	18.9	28.1	76	11.4	26.8
>40	71	4.2	18.4	89	20.9	21.2	160	13.5	21.6
Hamilton-Norwood pattern									
Type IIIv	55	8.3	20.0	70	23.6	18.9	125	16.9	20.8
Type IV	62	4.2	17.7	49	15.9	25.7	111	9.3	22.3
Type V	39	0.6	21.7	48	22.0	23.4	87	12.4	24.9
Race									
White	140	4.6	19.9	140	21.5	22.9	280	13.1	23.0
Nonwhite	16	5.8	18.6	27	17.6	20.0	43	13.2	20.1
Duration of hair loss (y)									
<5	40	5.9	19.9	39	20.9	24.8	79	13.3	23.5
5-10	71	8.3	20.3	76	22.2	21.3	147	15.5	21.9
>10	45	-1.8	17.1	52	18.9	22.6	97	9.3	22.6

*Intent-to-treat population and last observation carried forward.

Compliance

Subject compliance was assessed from use of study drug. The mean number of days subjects were exposed to study medication and the actual/estimated daily study drug use were similar for the active and placebo groups. Mean amount of study drug used per day for each group was 2.2 g.

Efficacy

TAHC. There was a steady increase in TAHCs over the 16-week, double-blind phase in subjects on the 5% MTF (Fig 1). The mean change in TAHC at weeks 8, 12, and 16 was significantly greater for the 5% MTF group as compared to placebo at all time points (15.5 vs 5.2, 19.8 vs 5.0, and 20.9 vs 4.7 TAHC, respectively, $P < .0001$ for each) (Fig 1). Overall, following 16 weeks on 5% MTF, there was a mean 13.4% increase in TAHC over baseline, whereas the placebo group showed a 3.4% increase. As shown in Table II, the response to MTF was not affected by age, Hamilton-Norwood hair loss pattern, race, or duration of hair loss.

Subject assessment. There was a statistically significant difference between 5% MTF and placebo ($P < .0001$) for subject assessment of improvement of hair loss condition. Of subjects on 5% MTF, 70.6% felt their hair loss had improved from baseline and only 6.2% felt that it had worsened (Table III). In comparison, 42.4% of subjects on placebo felt their hair loss had improved from baseline, and 19.2% of subjects felt their hair loss had worsened. The subject assessment difference was more striking for the

Table III. Summary of efficacy at week 16*

Subject assessment of hair loss condition	Placebo (n = 172)	5% MTF (n = 180)
	No. (%)	No. (%)
-3: Significantly worse	0	0
-2: Moderately worse	8 (4.7)	1 (0.6)
-1: Slightly worse	25 (14.5)	10 (5.6)
0: No change	56 (32.6)	32 (17.8)
+1: Slightly improved	36 (20.9)	41 (22.8)
+2: Moderately improved	28 (16.3)	47 (26.1)
+3: Significantly improved	9 (5.2)	39 (21.7)
Data not available	10 (5.8)	10 (5.6)

*Intent-to-treat population.

subjects who felt they had moderate or marked hair growth: 47.8% on 5% MTF vs 21.5% on placebo (Table III). The subject's age, Hamilton-Norwood hair loss pattern, race, or duration of hair loss did not affect the subject results.

GPR. In the blinded GPR by the expert panel of investigators, there was a statistically significant difference between 5% MTF and placebo ($P < .0001$). At week 16, 38.3% of subjects on 5% MTF were rated as having increased hair growth compared to 5.2% on placebo. The percentage of subjects who were rated as having moderate or marked growth was 7.8% on 5% MTF versus 0.6% on placebo (Table IV). Representative photographs are shown in Figs 2 and 3.

Safety

In the double-blind phase of the study, the overall incidence of AEs was similar in the placebo and

Table IV. Frequency of global photographic review scores at week 16 compared to baseline by treatment group*

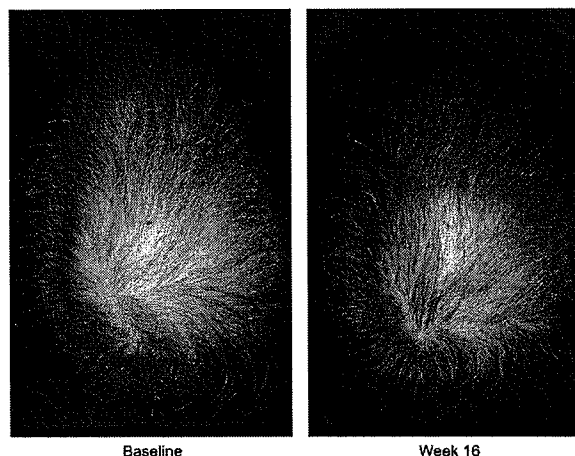
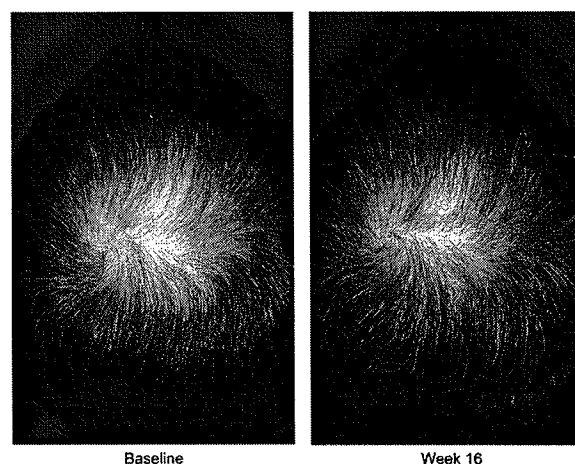
GPR score for hair loss	Placebo (n = 172) No. (%)	5% MTF (n = 180) No. (%)
-3 = Greatly decreased	0	0
-2 = Moderately decreased	0	0
-1 = Minimally decreased	4 (2.3)	0
0 = No change	134 (77.9)	94 (52.2)
+1 = Minimally increased	8 (4.7)	55 (30.6)
+2 = Moderately increased	1 (0.6)	14 (7.8)
+3 = Greatly increased	0	0
Data not available	25 (14.5)	17 (9.4)

GPR, Global photographic review.

*Intent-to-treat population.

active groups (46.5% in the placebo group and 45.6% in the 5% MTF group). The incidence of potential drug-related AEs was 6.7% for placebo and 7% for active drug. Only headache (placebo 1.2%, 5% MTF 1.7%), pruritus (placebo 0%, 5% MTF 1.1%), rash (placebo 0%, 5% MTF 1.1%), and pain (placebo 1.2%, 5% MTF <1%) occurred in more than 1% of subjects in either treatment group. Dryness/scaling, erythema, and/or folliculitis were surprisingly common at baseline (14.0% of placebo-treated subjects and 14.4% of 5% MTF-treated subjects), and there was no significant worsening of any of these signs of irritation in these subjects in either treatment group during the study (Table V). Overall, at the end of the 16-week placebo-controlled study, only 8.1% of those on placebo and 7.2% of those on 5% MTF showed any signs of irritation. Symptoms of irritation (stinging, burning, itching) occurred in 2.3% of those on placebo compared with 5.6% of those on 5% MTF, with itching (1.2% of those on placebo vs 4.4% of those on 5% MTF) accounting for the majority of the difference in groups. Most signs and symptoms were mild and intermittent in nature and only 8 of 172 subjects on placebo and 5 of 180 subjects on 5% MTF had greater than moderate levels of irritation at any time during the double-blind phase of the study.

There was no significant change in the overall incidence of AEs in the open-label phase of the study compared with the double-blind phase. The incidence of potential drug-related AEs in the open-label phase of the study remained low, with no AE occurring in more than 3% of study subjects: headache (2.1%); hypertension (1.4%); photosensitivity, nausea, weight gain, paresthesia, acne, pruritus, and rash each occurring in fewer than 1% of subjects. At the conclusion of the open-label phase, the signs of

**Fig 2.** Subject, 41 years old, with Hamilton-Norwood type V MPHL, rated as having moderate hair growth by expert panel at week 16 on 5% MTF.**Fig 3.** Subject, 33 years old, with Hamilton-Norwood type IV MPHL, rated as having moderate hair growth by expert panel at week 16 on 5% MTF.

irritation were not vastly different than those exhibited at baseline but were more than those shown at the end of the double-blind phase (15/143 or 10.5%). Symptoms of irritation remained low at 2.9% overall. Again, most signs and symptoms were mild and intermittent in nature.

There were no drug-related serious AEs reported in the double-blind or open-label phases of the study in the placebo or 5% MTF groups.

There were no clinically significant laboratory abnormalities in subjects either on placebo or on 5% MTF. Additionally, there was no pattern of clinically relevant changes in vital signs (blood pressure, pulse, or body weight) in either phase of the study in subjects using 5% MTF.

Two subjects on placebo and one subject on 5% MTF in the double-blind phase, and 3 subjects on 5%

Table V. Subjects with scalp irritation*

Study phase	Treatment group	Signs of scalp irritation (investigator assessed)				Symptoms of scalp irritation (subject assessed)			
		Dryness/ scaling No. (%)	Folliculitis No. (%)	Erythema No. (%)	Overall No. (%)	Burning No. (%)	Itching No. (%)	Stinging No. (%)	Overall No. (%)
Double-blind	Baseline								
	5% MTF (n = 180)	15 (8.3)	4 (2.2)	12 (6.7)	26 (14.4)	0	2 (1.1)	0	2 (1.1)
	Placebo (n = 172)	15 (8.7)	3 (1.7)	12 (7.0)	24 (14.0)	0	1 (0.6)	0	1 (0.6)
	Week 16								
	5% MTF (n = 180)	5 (2.8)	2 (1.1)	7 (3.9)	13 (7.2)	3 (1.7)	8 (4.4)	4 (2.2)	10 (5.6)
Open-label	Placebo (n = 172)	7 (4.1)	2 (1.2)	8 (4.7)	14 (8.1)	2 (1.2)	2 (1.2)	0	4 (2.3)
	Weeks 52/68 (n = 143)	5 (3.5)	7 (4.9)	9 (6.3)	15 (10.5)	2 (1.4)	5 (3.5)	2 (1.4)	5 (3.5)

*Includes slight or moderate degree.

MTF in the open-label phase had blood drawn to determine serum minoxidil levels secondary to an increase in blood pressure and/or body weight. The serum minoxidil levels were 1.17, 1.12, 1.02, and 0.397 $\mu\text{g/mL}$ in subjects on 5% MTF and less than 0.350 $\mu\text{g/mL}$ in subjects on placebo. All levels are within the range of serum levels seen with MTS, consistent with PK study results and well below the 21- $\mu\text{g/mL}$ threshold for cardiac-related events with minoxidil.

DISCUSSION

Delivery of topical medications into the scalp is challenging. To be effective, (1) a majority of the medication must be delivered to the scalp, and medication lost on the hair or surrounding skin must be minimized; (2) the drug must be readily released from the vehicle; and (3) the drug must penetrate either the epidermis/outer root sheath of the infundibulum and/or the follicular canal and the protective layers that surround the hair shaft. Moreover, to ensure compliance, the medication must be cosmetically acceptable, especially if it is to be used daily and long term. This means it should be quick to dry, nongreasy, and should not affect the integrity of the hair by making it dry or brittle. Ideally, the constituents of the vehicle should themselves be nonirritating and of low allergic potential.

Since 1997, 5% MTS has been available OTC. GPR documents hair growth in 54% to 62% of men with Hamilton-Norwood pattern IIIv, IV, and V after 48 weeks of 5% MTS.¹² However, the novel foam vehicle utilized in this study appears to offer certain advantages over the solution vehicle, including the absence of propylene glycol (a potential irritant), the ability to limit spread beyond the intended application site, and less time to dry after application. Its enhanced cosmetic acceptability may also increase

compliance with treatment, increasing the overall results with topical minoxidil. The mean increase at 16 weeks in both absolute TAHC and the change in TAHC relative to baseline was statistically significant ($P < .001$) between 5% MTF and placebo (20.9 vs 4.7 nonvellus hairs and 13.4% vs 3% total nonvellus hairs, respectively). Subjects on 5% MTF noted a mean 70.6% increase in hair growth versus 42.4% of subjects on placebo.

The incidence of pruritus with 5% MTF was 1.1% versus 6% seen in a separate trial of 5% MTS.¹² Overall, the incidence of irritation seen at baseline actually decreased during the study with both the foam vehicle and 5% MTF.

We conclude that the new 5% MTF preparation is a safe and effective treatment for MPHL.

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